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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,256	06/14/2005	Tapio Lankinen	1300-142	1261
6449	7590	12/04/2007		
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			EXAMINER HAGHIGHATIAN, MINA	
			ART UNIT	PAPER NUMBER
			1616	
			NOTIFICATION DATE	DELIVERY MODE
			12/04/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/509,256	Applicant(s) LANKINEN ET AL.	
	Examiner Mina Haghighatian	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/04 & 11/05 & 07/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide adequate support for "hydrocarbon, perfluorinated ether, fluorinated ether, perfluorinated hydrocarbon, fluorinated hydrocarbon, any other alcohol or hydrocarbon".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. Specifically, the term "abraded suspended" is indefinite and not proper English.

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Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 13, the term "an effect below that required for crushing..." is indefinite because it is not known to one of ordinary skill in the art what the "effect" is.

In claim 6, the term "a certain desired size range or ranges" is indefinite because one of ordinary skill in the art would not be able to determine what the "desired size range" the inventor had in mind.

In claims 12 and 17, the terms "any other sugar" and "any other compound used as a carrier" are indefinite because the scope of such terms or limitations are not clearly known to one of ordinary skill in the art.

In claim 10, the term "at least partly covered particles smaller in size than said carrier" is indefinite because it is not clear what carrier particles the claim is comparing, since in claim 1, it appears that all carrier particles are abraded.

The term "essentially" in claims 1, 13 and 18 is a relative term which renders the claim indefinite. The term "essentially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "small" in claims 11 is a relative term which renders the claim indefinite. The term "small" is not defined by the claim, the specification does not

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provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 4 recites the limitation "cooled". There is insufficient antecedent basis for this limitation in the claim. The preceding claims do not recite any step of heating the suspension and thus it is not clear why it would be necessary to cool the suspension.

Claim 11 recites the limitation "the small sized particles". There is insufficient antecedent basis for this limitation in the claim. The preceding claims 1 and 10, which claim 11 depends on, do not recite any size limitation for the particles.

Claims 7, 12 and 17 are employing an improper Markush-type language. See MPEP 608.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S.

patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Staniforth et al (WO 0200197 A1).

Staniforth et al teach method of making particles for use in a pharmaceutical composition. The method comprises excipient particles comprising a milling step in which particles of an excipient material in the presence of an additive material. The particles are of small size and the milling requires relatively low input of time and energy (see abstract). Preferably the **milling is wet**. The liquid medium may be aqueous or **non-aqueous**, high or low volatility as long as it does not dissolve the excipient particles. The method also comprises the step of removing the liquid after the milling step. That may be accomplished by sieving followed by spray drying, or by evaporation of the liquid. The composite excipient particles produced after the milling step may be of a suitable size for inhalation (see page7). Where the milling step is wet milling, the suspension or slurry may be spray dried directly after the milling step. The particles are then filtered (see page 8). The said compositions include powders for dry powder inhalers, suspensions for use in pressurized metered dose inhalers. The active agents include bronchodilators, steroids, polypeptides such

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as insulin, analgesics, etc (see pages 8-14). The excipient is preferably **lactose** (see page 14). The compositions may also contain a **carrier** such as **lactose**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jinks et al (WO 2002030394).

Jinks et al teach medicinal aerosol formulations. The carrier particles are preferably **lactose** and the particles are dispersed in a **propellant**. The medicaments include bronchodilators, corticosteroids, hormones, peptides, etc. The bulking agent is typically **lactose** and is prepared by forming a slurry of

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lactose in a low volatility solvent such as ethanol. In Example 1, α -lactose monohydrate is dispersed in anhydrous ethanol. The formulation was micronized by a fluid energy milling and then placed in a mixer.

While Jinks et al does not specifically disclose the method steps as claimed in the instant applications, there is adequate disclosure to one of ordinary skill in the art to make and use the invention as claimed. In other words, Jinks et al are teaching the advantages of treating carrier particles such as lactose for use in delivering active agents in powder form to the respiratory system. The steps disclosed by Jinks et al are either the same or very similar to the steps recited in the instant claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an

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invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **1-2, 12-15 and 18** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 14-16 of U.S. Patent No. 6,616,945. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are anticipated by the reference claims. In other words, all that is recited in the instant claims is generic to the reference claims. Specifically, the method of treating a particulate carrier for inhalation comprising abraded and suspended particles of a carrier such as lactose as claimed in the instant claims is anticipated by the method for preparing a physically stable and homogenous powdered pharmaceutical preparation to be inhaled comprising an active agent and an additive. The method steps and the other limitations are either the same or very similar.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'M. Haghighatian', enclosed within a large, loopy oval shape.

Mina Haghighatian
Patent Examiner
November 23, 2007